



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE *et al.*

Appl. No.: 09/357,737

Filed: July 19, 1999

For: **Inducing Cellular Immune
Responses to Hepatitis C Virus
Using Peptide and Nucleic Acid
Compositions**

Confirmation No.: 9669

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket: 2060.0030005/PAJ/M-M

Second Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

In accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, AA100 to AH100, cited on the attached Form PTO-1449 are not submitted. Copies of all other documents are provided.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

The documents cited in this Second Supplemental Information Disclosure Statement are of general relevance to the claimed invention.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: Nov. 29, 2004

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FORM PTO-1449

ATTY. DOCKET NO.

2060.0030005

APPLICATION NO.

09/357,737

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT**

APPLICANT(S)

SETTE *et al.*

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July 19, 1999

ART UNIT

1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA100	4,235,877	11/25/1980	Fullerton			06/27/1979
	AB100	4,487,715	12/11/1984	Nitecki <i>et al.</i>			07/09/1982
	AC100	4,599,230	07/08/1986	Milich <i>et al.</i>			03/09/1984
	AD100	4,837,028	06/06/1989	Allen			12/24/1986
	AE100	5,013,548	05/07/1991	Haynes <i>et al.</i>			01/21/1988
	AF100	5,128,319	07/07/1992	Arlinghaus			09/20/1989
	AG100	5,736,142	04/07/1998	Sette <i>et al.</i>			09/14/1994
	AH100	5,783,567	07/21/1998	Hedley <i>et al.</i>			01/22/1997
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL100	EP 0 378 881	06/09/1993	Europe			Yes No
	AM100	EP 0 429 816	06/05/1991	Europe			Yes No
	AN100	EP 0 433 242	06/19/1991	Europe			Yes No
	AO100	WO 93/03764	03/04/1993	WIPO			Yes No
	AP100	WO 94/20127	09/15/1994	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	100	Alexander, J., <i>et al.</i> , "Development of High Potency Universal DR-Restricted Helper Epitopes by Modification of High Affinity DR-Blocking Peptides," <i>Immunity</i> 1:751-761, Cell Press (1994)
	AS	100	Arndt, S.O., <i>et al.</i> , "Selection of the MHC Class II-Associated Peptide Repertoire by HLA-DM," <i>Immunol. Res.</i> 16:261-272, Humana Press (December 1997)
	AT	100	Barouch, D., <i>et al.</i> , "HLA-A2 Subtypes Are Functionally Distinct in Peptide Binding and Presentation," <i>J. Exp. Med.</i> 182:1847-1856, Rockefeller University Press (1995)

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AL101		WO 95/07707	03/23/1995	WIPO			Yes No
AM101		WO 96/22067	07/25/1996	WIPO			Yes No
AN101		WO 97/41440	11/06/1997	WIPO			Yes No
AO101		WO 97/34617	09/25/1997	WIPO			Yes No
AP101		WO 01/00225	01/04/2001	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	101	Bender, A., <i>et al.</i> , "Improved methods for the generation of dendritic cells from nonproliferating progenitors in human blood," <i>J. Immunol. Methods</i> 196:121-135, Elsevier Science (1996)
AS	101	Ben-Yedidia, T., and Arnon, R., "Design of peptide and polypeptide vaccines," <i>Curr. Opin. Biotechnol.</i> 8:442-448, Current Biology, Ltd. (1997)
AT	101	Carbone, F.R., and Bevan, M.J., "Induction of Ovalbumin-Specific Cytotoxic T Cells by In Vivo Peptide Immunization," <i>J. Exp. Med.</i> 169:603-612, Rockefeller University Press (1989)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>102</u>	Carbone, F.R., <i>et al.</i> , "Induction of Cytotoxic T Lymphocytes by Primary In Vitro Stimulation with Peptides," <i>J. Exp. Med.</i> 167:1767-1779, Rockefeller University Press (1988)
	AS	<u>102</u>	Cassell, D., and Forman, J., "Linked Recognition of Helper and Cytotoxic Antigenic Determinants for the Generation of Cytotoxic T Lymphocytes," <i>Ann. N.Y. Acad. Sci.</i> 532:51-60, New York Academy Of Sciences (1991)
	AT	<u>102</u>	Deres, K., <i>et al.</i> , "In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine," <i>Nature</i> 342:561-564, Nature Publishing Group (1989)

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AR	<u>103</u>	del Guercio, M-F., <i>et al.</i> , "Potent immunogenic short linear peptide constructs composed of B cell epitopes and Pan DR T Helper Epitopes (PADRE) for antibody responses <i>in vivo</i> ," <i>Vaccine</i> 15:441-448, Elsevier Science (March 1997)
AS	<u>103</u>	DiBrino, M., <i>et al.</i> , "Endogenous Peptides with Distinct Amino Acid Anchor Residue Motifs Bind to HLA-A1 and HLA-B8," <i>J. Immunol.</i> 152:620-631, American Association of Immunologists (1994)
AT	<u>103</u>	DiBrino, M., <i>et al.</i> , "The HLA-B14 Peptide Binding Site Can Accommodate Peptides with Different Combinations of Anchor Residues," <i>J. Biol. Chem.</i> 269:32426-32434, American Society for Biochemistry and Molecular Biology (1994)

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	AR	<u>104</u>	Donnelly, J.J., <i>et al.</i> , "DNA Vaccines," <i>Annu. Rev. Immunol.</i> 15:617-648, Annual Reviews Inc. (April 1997)
	AS	<u>104</u>	Francis, M.J., <i>et al.</i> , "Non-responsiveness to a foot-and-mouth disease virus peptide overcome by addition of foreign helper T-cell determinants," <i>Nature</i> 330:168-170, Nature Publication Group (1987)
	AT	<u>104</u>	Fynan, E.F., <i>et al.</i> , "DNA vaccines: Protective immunizations by parental, mucosal, and gene-gun inoculations," <i>Proc. Natl. Acad. Sci. USA</i> 90:11478-11482, National Academy of Sciences (1993)

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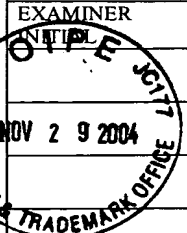
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	AR	<u>105</u>	Gileadi, U., <i>et al.</i> , "Effect of epitope flanking residues on the presentation of N-terminal cytotoxic T lymphocyte epitopes," <i>Eur. J. Immunol.</i> 29:2213-2222, WILEY-VCH Verlag GmbH (July 1999)
	AS	<u>105</u>	Golvano, J., <i>et al.</i> , "Polarity of immunogens: implications for vaccine design," <i>Eur. J. Immunol.</i> 20:2363-2366, VCH Verlagsgesellschaft mbH (1990)
	AT	<u>105</u>	Gulukota, K., <i>et al.</i> , "Two Complementary Methods for Predicting Peptides Binding Major Histocompatibility Complex Molecules," <i>J. Mol. Biol.</i> 267:1258-1267, Academic Press Limited (April 1997)

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AR	106	Hahn, Y.S., <i>et al.</i> , "CD8 ⁺ T Cell Recognition of an Endogenously Processed Epitope is Regulated Primarily by Residues within the Epitope," <i>J. Exp. Med.</i> 176:1335-1341, Rockefeller University Press (1992)
AS	106	Hahn, Y.S., <i>et al.</i> , "Presentation of Viral Antigen to Class I Major Histocompatibility Complex-Restricted Cytotoxic T Lymphocyte. Recognition of an Immunodominant Influenza Hemagglutinin Site by Cytotoxic T Lymphocyte is Independent of the Position of the Site in the Hemagglutinin Translation Product," <i>J. Exp. Med.</i> 174:733-736, Rockefeller University Press (1991)
AT	106	Hammer, J., <i>et al.</i> , "Precise Prediction of Major Histocompatibility Complex Class II-Peptide Interaction Based on Peptide Side Chain Scanning," <i>J. Exp. Med.</i> 180:2353-2358, Rockefeller University Press (1994)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>107</u>	Hill, C.M., <i>et al.</i> , "Exploration of Requirements for Peptide Binding to HLA DRB1*0101 and DRB1*0401," <i>J. Immunol.</i> 152:2890-2898, American Association of Immunologists (1994)
	AS	<u>107</u>	Huczko, E.L., <i>et al.</i> , "Characteristics of Endogenous Peptides Eluted from the Class I MHC Molecule HLA-B7 Determined by Mass Spectrometry and Computer Modeling," <i>J. Immunol.</i> 151:2572-2587, American Association of Immunologists (1993)
	AT	<u>107</u>	Ishioka, G.Y., <i>et al.</i> , "Class I MHC-restricted, peptide specific cytotoxic T lymphocytes generated by peptide priming in vivo," in <i>Vaccines90: Modern Approaches to New Vaccines Including Prevention of AIDS</i> , Brown, F., <i>et al.</i> , eds., Cold Spring harbor Laboratory Press, Cold Spring Harbor, NY, pp. 7-11 (1990)

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	AR	<u>108</u>	Ishioka, G.Y., <i>et al.</i> , "Induction of Class I MHC-Restricted, Peptide-Specific Cytolytic T Lymphocytes by Peptide Priming In Vivo," <i>J. Immunol.</i> 143:1094-1100, American Association of Immunologists (1989)
	AS	<u>108</u>	Jardetzky, T.S., <i>et al.</i> , "Peptide binding to HLA-DR1: a peptide with most residues substituted to alanine retains MHC binding," <i>EMBO J.</i> 9:1797-1803, Oxford University Press (1990)
	AT	<u>108</u>	Kast, W.M., <i>et al.</i> , "Protection against lethal Sendai virus infection by <i>in vivo</i> priming of virus-specific cytotoxic T lymphocytes with a free synthetic peptide," <i>Proc. Natl. Acad. Sci. USA</i> 88:2283-2287, National Academy of Sciences (1991)

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	AR	<u>109</u>	Kondo, A., <i>et al.</i> , "Two distinct <i>HLA-A*0101</i> -specific submotifs illustrate alternative peptide binding modes," <i>Immunogenetics</i> 45:249-258, Springer-Verlag (January 1997)
	AS	<u>109</u>	Kubitscheck, U., <i>et al.</i> , "Peptide Binding to Class I Molecules of the Major Histocompatibility Complex on the Surface of Living Target Cells," <i>Scand. J. Immunol.</i> 36:341-348, Blackwell Scientific Publications (1992)
	AT	<u>109</u>	Kubo, R.T., <i>et al.</i> , "Definition of Specific Peptide Motifs for Four Major <i>HLA-A</i> Alleles," <i>J. Immunol.</i> 152:3913-3924, American Association of Immunologists (1994)

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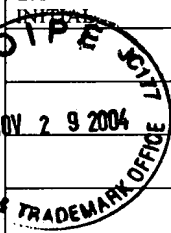
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	AR	<u>110</u>	Kumar, A., <i>et al.</i> , "Universal T Helper Cell Determinants Enhance Immunogenicity of a <i>Plasmodium falciparum</i> Merozoite Surface Antigen Peptide," <i>J. Immunol.</i> 148:1499-1505, American Association of Immunologists (1992)
	AS	<u>110</u>	Lasarte, J-J., <i>et al.</i> , "Induction of Cytotoxic T Lymphocytes in Mice against the Principal Neutralizing Domain of HIV-1 by Immunization with an Engineered T-Cytotoxic-T-Helper Synthetic Helper Peptide Construct," <i>Cell. Immunol.</i> 141:211-218, Academic Press Inc. (1992)
	AT	<u>110</u>	Madden, D.R., <i>et al.</i> , "The structure of HLA-B27 reveals nonamer self-peptides bound in an extended conformation," <i>Nature</i> 353:321-325, Nature Publishing Group (1991)

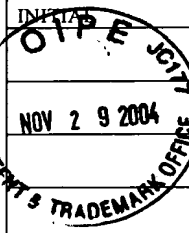
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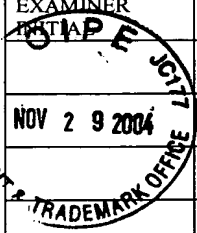
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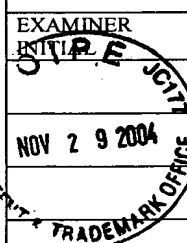
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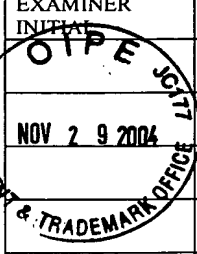
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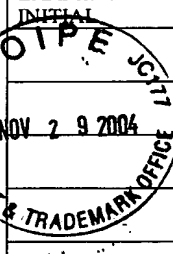
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	AR	<u>124</u>	Wiesmüller, K-H., <i>et al.</i> , "Lipopeptide-Helper-T-Cell Epitope-CTL Epitope Conjugate Induces Antibodies Against the CTL Epitope," <i>Innovation Perspective Solid Phase Synthesis Collect. Papers, Int. Symp. 2nd</i> , pp. 499-502 (1991)
	AS	<u>124</u>	Wiesmüller, K-H., <i>et al.</i> , "Novel low-molecular-weight synthetic vaccine against foot-and mouth disease containing a potent B cell and macrophage activator," <i>Vaccine</i> 7:29-33, Butterworth & Co. (1989)
	AT	<u>124</u>	Yewdell, J.W., and Bennink, J.R., "Immunodominance in Major Histocompatibility Complex Class I-Restricted T Lymphocyte Responses," <i>Annu. Rev. Immunol.</i> 17:51-88, Annual Reviews Inc. (April 1999)

EXAMINER

DATE CONSIDERED

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FORM PTO-1449

ATTY. DOCKET NO.

2060.0030005

APPLICATION NO.

09/357,737

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT**

APPLICANT(S)

SETTE *et al.*

FILING DATE

July 19, 1999

ART UNIT

1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>125</u>	Zhou, X., <i>et al.</i> , "In vivo primary induction of virus-specific CTL by immunization with 9-mer synthetic peptides," <i>J. Immunol. Methods</i> 153:193-200, Elsevier Science Publishers B.V. (1992)
	AS	<u>125</u>	Zinkernagel, R.M., <i>et al.</i> , "The Lymphoreticular System in Triggering Virus Plus Self-Specific Cytotoxic T Cells: Evidence for T Help," <i>J. Exp. Med.</i> 147:897-911, Rockefeller University Press (1978)
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EXAMINER

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE *et al.*

Appl. No.: 09/357,737

Filed: July 19, 1999

For: **Inducing Cellular Immune
Responses to Hepatitis C Virus
Using Peptide and Nucleic Acid
Compositions**

Confirmation No.: 9669

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket: 2060.0030005/PAJ/M-M

Third Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

In accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, AA200 to AB200, cited on the attached Form PTO-1449 are not submitted. Copies of all other documents are provided.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

The documents cited in this Third Supplemental Information Disclosure Statement generally relate to HCV peptides.

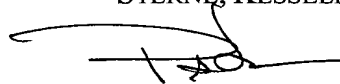
This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Peter A. Jackman", is written over a horizontal line.

Peter A. Jackman
Attorney for Applicants
Registration No. 45,986

Date: Nov. 29, 2004

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1349

NOV 29 2004

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT

ATTY. DOCKET NO.
2060.0030005

APPLICATION NO.
09/357,737

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SETTE *et al.*

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA200	5,980,899	11/09/1999	Berzofsky <i>et al.</i>			06/10/1992
	AB200	6,150,087	11/21/2000	Chien			05/18/1995
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL200	WO 95/25122	09/21/1995	WIPO			Yes No
	AM200	WO 97/34621	09/25/1997	WIPO			Yes No
	AN200	EP 0 318 216 B1	05/31/1989	Europe			Yes No
	AO						Yes No
	AP						Yes No

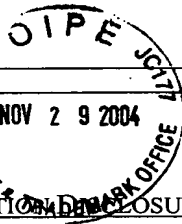
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>200</u>	Cerny, A., <i>et al.</i> , "Induction <i>in vitro</i> of a primary human antiviral cytotoxic T cell response," <i>Eur. J. Immunol.</i> 25:627-630, VCH Verlagsgesellschaft (1995)
	AS	<u>200</u>	Chang, K-M., <i>et al.</i> , "Identification of HLA-A3 and -B7-Restricted CTL Response to Hepatitis C Virus in Patients with Acute and Chronic Hepatitis C," <i>J. Immunol.</i> 162:1156-1164, American Association of Immunologists (January 1999)
	AT	<u>200</u>	Kita, H., <i>et al.</i> , "HLA B44-Restricted CTL Response to HCV Nucleocapsid Protein Derived Peptides from Different HCV Isolates," <i>Hepatology AASLD Abstract No. 631:214A</i> , Williams & Wilkins (1993)

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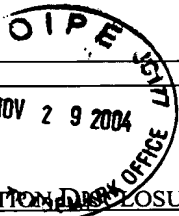
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	201	Koziel, M.J., <i>et al.</i> , "Hepatitis C Virus (HCV)-Specific Cytotoxic T Lymphocytes Recognize Epitopes in the Core and Envelope Proteins of HCV," <i>J. Virol.</i> 67:7522-7532, American Society For Microbiology (1993)
	AS	201	Lamonaca, V., <i>et al.</i> , "Conserved Hepatitis C Virus Sequences are Highly Immunogenic for CD4 ⁺ T Cells: Implications for Vaccine Development," <i>Hepatology</i> 30:1088-1098, Williams & Wilkins (October 1999)
	AT	201	Oseroff, C., <i>et al.</i> , "Pools of lipidated HTL-CTL constructs prime for multiple HBV and HCV CTL epitope responses," <i>Vaccine</i> 16:823-833, Elsevier Science (April 1998)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>202</u>	Rammensee, H-G., <i>et al.</i> , "MHC ligands and peptide motifs: first listing," <i>Immunogen.</i> 41:178-228, Springer-Verlag (1995)
	AS	<u>202</u>	Sarobe, P., <i>et al.</i> , "Enhanced In Vitro Potency and In Vivo Immunogenicity of a CTL Epitope from Hepatitis C Virus Core Protein following Amino Acid Replacement at Secondary HLA-A2.1 Binding Positions," <i>J. Clin. Invest.</i> 102:1239-1248, American Society for Clinical Investigation (September 1998)
	AT	<u>202</u>	Schulz, M., <i>et al.</i> , "Peptide-induced antiviral protection by cytotoxic T cells," <i>Proc. Natl. Acad. Sci. USA</i> 88:991-993, National Academy of Sciences (1991)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	203	Shirai, M., <i>et al.</i> , "Use of Intrinsic and Extrinsic Helper Epitopes for In Vivo Induction of Anti-Hepatitis C Virus Cytotoxic T Lymphocytes (CTL) with CTL Epitope Peptide Vaccines," <i>J. Infect. Dis.</i> 173:24-31, University of Chicago Press (1996)
	AS	203	Wentworth, P.A., <i>et al.</i> , "Identification of A2-restricted hepatitis C virus-specific cytotoxic T lymphocyte epitopes from conserved regions of the viral genome," <i>Int. Immunol.</i> 8:651-659, Oxford University Press (1996)
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